or fax it to 301–436–2804 or 1–800–573–0846.

(3) If the information on the form is incomplete or illegible when FDA receives it, FDA will return the form to you for revision, provided that your mailing address or fax number is legible and valid. When returning a cancellation form for revision, FDA will use the means by which the cancellation was received by the agency (*i.e.*, by mail or fax).

(4) FDA will enter complete and legible mailed and faxed cancellations into its registration system, along with CD-ROM cancellations, as soon as practicable, in the order FDA receives them.

(5) FDA will then mail to the address or fax to the fax number on the cancellation form a copy of the cancellation as entered and confirmation of the cancellation. When responding to a cancellation, FDA will use the means by which the form was received by the agency (*i.e.*, by mail or fax).

(6) If any information you previously submitted was incorrect at the time of submission, you must immediately resubmit your cancellation.

(7) Your registration will be considered cancelled once FDA enters your facility's cancellation data into the registration system and the system generates a confirmation.

(e) *Cancellation by CD-ROM for multiple submissions.* If, for example, you do not have reasonable access to the Internet through any of the methods described in §1.231(a), you may cancel your facilities' registrations using a CD-ROM.

(1) Registrants submitting their cancellations in CD-ROM format must use ISO 9660 (CD-R or CD-RW) data format.

(2) Cancellation files must be submitted on a PDF rendition of the cancellation form (Form 3537a) and be accompanied by one signed copy of the certification statement on the cancellation form.

(3) Each submission on the CD-ROM must contain the same preferred mailing address in the appropriate block on Form 3537.

(4) The CD-ROM may contain cancellations for as many facilities as needed up to the CD-ROM's capacity.

(5) The cancellation for each facility on the CD-ROM must have a unique file name up to 32 characters long, the first part of which may be used to identify the parent company.

(6) You must mail the CD-ROM to U.S. Food and Drug Administration (HFS–681), 5600 Fishers Lane, Rockville, MD 20857.

(7) If FDA receives a CD-ROM that does not comply with these specifications, it will return the CD-ROM to the registrant unprocessed.

(8) FDA will enter CD-ROM submissions that meet the specifications into its registration system, along with complete and legible mailed and faxed submissions, as soon as practicable, in the order FDA receives them.

(9) For each facility on the CD-ROM, FDA will mail to the preferred mailing address a copy of the cancellation(s) as entered and confirmation of the cancellation.

(10) If any information you previously submitted was incorrect at the time of submission, you must immediately resubmit your cancellation.

(11) Your registration will be considered cancelled once FDA enters your facility's cancellation data into the registration system and the system generates a confirmation.

[68 FR 58960, Oct. 10, 2003 as amended at 73 FR 15883, Mar. 26, 2008]

ADDITIONAL PROVISIONS

§1.240 What other registration requirements apply?

In addition to the requirements of this subpart, you must comply with the registration regulations found in part 108 of this chapter, related to emergency permit control, and any other Federal, State, or local registration requirements that apply to your facility.

§1.241 What are the consequences of failing to register, update, or cancel your registration?

(a) Section 301 of the act (21 U.S.C. 331) prohibits the doing of certain acts or causing such acts to be done. Under section 302 of the act (21 U.S.C. 332), the United States can bring a civil action in Federal court to enjoin a person who commits a prohibited act. Under section 303 of the act (21 U.S.C. 333),